Pharmacists Allowed to Prescribe COVID-19 Antiviral

Pharmacists can now prescribe nirmatrelvir-ritonavir (Paxlovid) with certain limitations under a revised Emergency Use Authorization (EUA) for the COVID-19 antiviral treatment.

The pills must be taken within 5 days of symptom onset, so enabling patients to obtain a prescription from pharmacists could expand access to timely treatment, Patrizia Cavazzoni, MD, director of the FDA’s Center for Drug Evaluation and Research, noted in a statement.

Allowing pharmacists to prescribe the treatment will improve access in communities with fewer physicians and advanced practice clinicians, the president of the Infectious Diseases Society of America pointed out in a statement. “Recent data show people who may be most in need of antiviral treatment for COVID-19, including Paxlovid, may not be receiving it because of where they live,” Daniel McQuillen, MD, said. “Barriers to treatment are particularly steep for many people of color and individuals with lower incomes who have been disproportionately impacted by COVID-19 and who live in underserved communities with fewer health care providers.”

But the president of the American College of Physicians (ACP) expressed concern about the FDA’s decision. The ACP “believes that more needs to be done to improve access to Paxlovid for treating COVID-19 infections in the outpatient setting,” Ryan Mire, MD, acknowledged in a statement. “However we believe that relaxing prescribing standards could jeopardize patient safety and undermine collaborative care.”

“The policy laid out by the FDA could remove the physician from the care process, preventing them from tracking potential adverse interactions,” Mire continued.

Nirmatrelvir-ritonavir is authorized to treat mild to moderate COVID-19 in nonhospitalized patients aged 12 years or older who are at high risk of progression to severe disease due to age, obesity, cancer, or chronic diseases such as type 1 or type 2 diabetes. (High-risk patients who have mild to moderate COVID-19 but are hospitalized for other reasons are also eligible.)

If people test positive for COVID-19, they should first consider seeking care from the health care professional who regularly provides it or at a test-to-treat site, the FDA recommends. Under the revised nirmatrelvir-ritonavir EUA, patients who test positive for COVID-19 and decide to seek a prescription from a pharmacist should provide electronic or printed health records less than a year old, including laboratory blood work, so the pharmacist can review them for liver or kidney problems. Patients also need a list of all medications they are taking so pharmacists can screen for drugs with potentially serious interactions with nirmatrelvir-ritonavir.

Evusheld Treatment Timing Set

People eligible for COVID-19 preexposure prophylaxis (PrEP) with the monoclonal antibody combination of tixagevimab and cilgavimab (Evusheld) should be treated every 6 months to maintain protection against infection, according to the recently revised Fact Sheet for Healthcare Providers.

Previously, the fact sheet did not recommend a specific dosing interval.

The combination of tixagevimab and cilgavimab, the only authorized therapy for COVID-19 PrEP, may be used in adults and children aged 12 years or older who have a moderately to severely compromised immune system because of a medical condition such as cancer or immunosuppressive treatments, or they’ve had a severe reaction to any of the COVID-19 vaccines or their components, according to its Emergency Use Authorization (EUA).

Under its EUA, the tixagevimab and cilgavimab combination is not a substitute for immunization in individuals for whom vaccination is recommended.

When the FDA first authorized the therapy’s emergency use in December 2021, the recommended dose was 150 mg of tixagevimab and 150 mg of cilgavimab. The agency doubled the recommended dose in late February to better protect against the Omicron subvariants BA.1 and BA.1.1. A recent study that had not been peer-reviewed reported that tixagevimab and cilgavimab, referred to as ADZ7442, still showed activity against BA.4 and BA.5, now the dominant circulating Omicron subvariants in the US.

New Device Okayed for Treating Pulmonary Hypertension in Newborns

The first device of its type to treat pulmonary hypertension in newborns recently received FDA approval.

Beyond Air’s LungFit PH generates nitric oxide gas from room air in conjunction with a ventilator to improve oxygenation, according to the FDA’s website. It is intended for newborns of at least 34 weeks’ gestation who have persistent pulmonary hypertension, which affects about 1 in every 1250 infants, according to information from the FDA. Risk factors include a difficult birth, birth asphyxia, infections such as pneumonia, and heart or lung problems.

Nitric oxide, a vasodilator, is approved in the US and dozens of other countries to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term newborns with persistent pulmonary hypertension, a Beyond Air news release stated.

The company is currently working to make LungFit PH available at select hospitals and plans a broader hospital launch in the first half of 2023, according to the release. — Rita Rubin

Note: Source references are available through embedded hyperlinks in the article text online.